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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/140,886 08/26/98 WILSON

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EXAMINER

HM22/0518

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ART UNIT

PAPER NUMBER

1638

DATE MAILED:

05/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/140,886

Applicant(s)
Wilson et al.

Examiner
Ousama Zaghmout

Group Art Unit
1638



☒ Responsive to communication(s) filed on Dec 6, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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STATUS OF APPLICATION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The amendment filed 12/06/1999 has been received (Paper No.7).
4. Status of claims:

Claims 1-22 are pending.

Claim Rejections - 35 U.S.C. § 112

1st paragraph

1. Claims 1 and 15 remain rejected under 35 U.S.C. 112, first paragraph, for not satisfying the requirements of the written description for the same reasons mentioned in the previous Office action.

Applicant's arguments filed on 12/06/1999 have been carefully considered, but not found to be persuasive for reasons listed below:

- A. Applicant asserts that the native regulatory element or elements already present in the donor DNA are sufficient and other heterologous promoters or regulator elements are not necessary

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(paragraph 1 in the REMARKS, page 1). This is not found persuasive. As mentioned previously in the Office action mailed 06/07/1999, pages 2-3, the claims are broadly drawn to a method of obtaining a transgenic plant having an improved agronomic characteristic by transforming plant cells of a recipient plant species with DNA fragments from DNA of a donor plant species. However, the specification does not teach the physical characteristics or the chemical properties of the nucleotide sequences that are encompassed in the claimed method of the invention. Neither the prior art nor the specification teaches that all of the said nucleotide sequences to have been known at the time when the application of the invention was filed. Accordingly, one of skill in the art would not have recognized the Applicants to have been in possession of transgenic plants obtained by the claimed methods. Therefore, these claims are rejected under 35 U.S.C. 112, first paragraph for failing to comply with the description of the invention requirement.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089,

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1096 (Fed. Cir. 1983)). See MPEP 2163.02: Standard for Determining Compliance With the Written Description Requirement.

2. Claims 1-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention as claimed for the reasons of record mentioned in the previous Office action.

Applicant's arguments filed on 12/06/1999 have been carefully considered, but not found to be persuasive for reasons listed below:

Applicant's argue that the specification provides adequate information to enable a person of ordinary skill in the art and /or use the invention. Applicant further argues that the native regulatory element(s) already present in the donor DNA are sufficient and other heterologous promoters or regulatory elements are not needed (last paragraph of page 1 extending to paragraph 1 of page 2, REMARKS). This is not found to be persuasive as the specification is not enabling for a method for obtaining a transgenic plant having an improved agronomic characteristics ^{where the method} comprises the steps in claim 1 or 15. The specification does not teach those skilled in the art how to make and use the invention as claimed as no transgenic plant with improved agronomic characteristics has been disclosed. The specification teaches only a variation for traits such as time to reach maturity, drought resistance, cold hardness, increased pest resistance, and stalk and root strength (see last paragraph in page 15 of the

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a

specification). The specification does not teach if ^atransgenic plant, if any, is resistant to a pest for example. the specification does not teach those skilled in the art a specific guidance for screening said transgenic plants for resistance to any pest; if a specific pest requires a specific way of handling during testing, if those skilled in the art have to screen every pest in order to find one that does not attack a transgenic plant; if said transgenic plant is resistant to pest due to the lack of virulence factors rather than the expression of a gene encoding a foreign protein resulting from the transformation process. Moreover, the specification does not teach what genes are encoded with the "DNA fragments" and if said gene will make the plant resistant to maturity rather than to pest resistance. Moreover, the specification is silent as to the criteria used to identify transgenic plants that express the improved agronomic traits or the co-suppression of the endogenous and the targeted gene if the inserted genes will be expressed in a way to allow the obtention of the desirable traits. Applicant has provided no specific guidance as to how to select the nucleotide sequences which will produce a protein or a polypeptide conferring the desired effect. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not. Hence, due to the lack of any working examples of the inventions, and the inability of one skilled in the art to predict which if any of all possible proteins which will be useful in the manner suggested, and the unpredictability of the field, it would require undue experimentation to practice the claims.

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Claim Rejections - 35 USC § 102

Claims 1-2, 8-9 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Masoud et al [Plant Molecular Biology. 1993. Vol. 21: 655-663] for the reasons of record specified in the previous Office action mailed 06/07/1999.

Applicant's arguments filed on 12/06/1999 have been carefully considered, but not found to be persuasive for reasons listed below:

Applicants argue that the invention requires no characterization of the donor DNA (such as its sequence) and no heterologous promoters or regulatory elements would be used (paragraph 2, page 2). This is not found persuasive as Applicant is arguing limitations which are not in the claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571-72, 7 USPQ2d 1057, 1064-1065 (Fed. Cir.), cert. denied, 488 U.S. 892 (1988) (Various limitations on which appellant relied were not stated in the claims; the specification did not provide evidence indicating these limitations must be read into the claims to give meaning to the disputed terms.).

Claim Rejections - 35 USC § 103

Claims 1-22 remain rejected under 35 U.S.C. § 103 as being unpatentable over Masoud et al [Plant Molecular Biology. 1993. Vol. 21: 655-663] in view of Hamilton et al [Proc

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Natl Acad Sci U S A. 1996 Sep 3;93(18):9975-9979] for the reasons of record specified in the previous Office action.

Applicant's arguments filed on 12/06/1999 have been carefully considered, but not found to be persuasive for reasons listed below:

A. Applicants argue ^{that} use of the present invention requires no characterization of the donor DNA (such as its sequence) and no heterologous promoters or regulatory elements would be used, ^{This argument has been addressed above.} instead of the native regulatory elements already present with the donor DNA. Applicant further argues that the intent of Hamilton et al is to characterize the donor DNA and that the present invention does not involve a method of characterization prior to or after transformation (paragraph 3, REMARKS). This is not found persuasive as Applicant has argued and discussed the references individually without clearly addressing the combined teaching. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicants' claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); in re Keller 642 F. 2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, it is not necessary that a reference actually

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suggest changes or possible improvements which applicants made. In re Scheckler, 438 F.2d 999, 10001, 168 USBQ 716, 717 (CCPA 1971). It is assumed that every reference relies to some extent on the knowledge of persons skilled in the art to complement that which is disclosed therein. Further, the person having ordinary skill in the art has a level of knowledge apart from the content of the references. In re Bode, 550 F.2d 656,660,193 USPQ 12, 16, (CCPA 1977); In re Jacoby, 309 F. 2d 513, 516, 135 USPQ 317,319 (CCPA 1962).

Moreover, the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Furthermore, these limitation presented by Applicant are not in the claims. Therefore, the teaching of Masoud et al and Hamilton et al take as a whole would make prima facie case of obviousness of the present invention as claimed unless proof of the contrary is provided for the reasons of record stated in the previous Office action.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

May 12, 2000

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

